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DATE MAILED: 10/02/2002

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------------|------------------|
| 09/903,327 | 07/10/2001 | Glen R. Nemerow | 22908-1228B | 7374 |
| 75 | 10/02/2002 | | | |
| STEPHANIE SEIDMAN HELLER EHRMAN WHITE & MCAULIFFE LLP 4350 LA JOLLA VILLAGE DRIVE, 7th FL. SAN DIEGO, CA 92122-1246 | | | EXAMINER | |
| | | | WEHBE, ANNE MARIE SABRINA | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1632 | 1. 1 |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application No. | Applicant(s) | | | |
|---|---------------------------|---|--|--|--|
| • | 09/903,327 | NEMEROW ET AL. | | | |
| Office Action Summary | Examiner | Art Unit | | | |
| | Anne M Wehbé | 1632 | | | |
| Th MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status | | | | | |
| 1) Responsive to communication(s) filed on | · | | | | |
| 2a) This action is FINAL . 2b) | This action is non-final. | | | | |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | | |
| closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. Disposition of Claims | | | | | |
| 4) Claim(s) 1-39 is/are pending in the application. | | | | | |
| 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | |
| 5) Claim(s) is/are allowed. | | | | | |
| 6) Claim(s) is/are rejected. | | | | | |
| 7) Claim(s) is/are objected to. | | | | | |
| 8) Claim(s) <u>1-39</u> are subject to restriction and/or election requirement. | | | | | |
| Application Papers | | | | | |
| 9) The specification is objected to by the Examiner. | | | | | |
| 10) The drawing(s) filed on is/are: a) □ accepted or b) □ objected to by the Examiner. | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). 11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner. | | | | | |
| If approved, corrected drawings are required in reply to this Office action. | | | | | |
| 12) The oath or declaration is objected to by the Examiner. | | | | | |
| Priority under 35 U.S.C. §§ 119 and 120 | | | | | |
| 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). | | | | | |
| a) ☐ All b) ☐ Some * c) ☐ None of: | | | | | |
| 1. Certified copies of the priority documents have been received. | | | | | |
| 2. Certified copies of the priority documents have been received in Application No. | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | |
| 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application). | | | | | |
| a) ☐ The translation of the foreign language provisional application has been received. 15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. | | | | | |
| Attachment(s) | | | | | |
| 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No. | 3) D No | erview Summary (PTO-413) Paper No(s) tice of Informal Patent Application (PTO-152) ner: | | | |

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DETAILED ACTION

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Restriction to one of the following inventions is required under 35 U.S.C. 121:

- Claims 1-27, drawn to bifunctional molecules, classified in class 530, subclass 387.3.
- II. Claims 28 and 35, drawn to a nucleic acid encoding a bifunctional molecule, classified in class 536, subclass 23.1.
- III. Claims 29-34, and 36-39, drawn to methods using and compositions comprising a vector and a bifunctional molecule, classified in classes 435, 530, and 514, subclasses 320.1, 387.3, and 44 respectively.

The inventions are distinct, each from the other because of the following reasons:

- 1) Inventions I and II are patentably distinct in that the fusion molecules/protein of invention I and the nucleic acid of invention II have substantially different structures, functions and properties, are made using substantially different techniques, and can be used for substantially different purposes. Please note in particular that the nucleic acid can be used in vitro hybridization assays and that the bifunctional molecule can be made by chemical synthesis or by the chemical conjugation of naturally occurring proteins.
- 2) Inventions I and II are patentably distinct from invention II in that the nucleic acid of invention II is not required for the methods and compositions of invention III, and in that the bifunctional molecule of invention I can be used for substantially different purposes than targeting vectors to

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specific cells either in vitro or in vivo. In particular, the bifunctional molecule can be used in simply in vitro binding assays or in purification columns.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, different classification, and different search requirements, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (703) 306-9156. The examiner can be reached Mon-Thurs and every other Friday from 9:30-7:00. If the examiner is not available, the examiner's supervisor, Deborah Reynolds, can be reached at (703) 305-4051. General inquiries should be directed to the group receptionist whose phone number is (703) 308-0196. The

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technology center fax number is (703) 308-4242, the examiner's direct fax number is (703) 746-7024.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D PRIMARY EXAMINER